



JUL 20 1999

K991860

Attachment VII:

**Summary of Safety and Effectiveness Information
[510(k) Summary]**

SUBMITTER Synthes (USA)
1690 Russell Road
Paoli, PA 19301
(610) 647-9700

Contact: Sheri L. Musgnung

DEVICE NAME: Synthes Cranial Flap Twist Clamp

COMMON OR USUAL NAME Plate, Cranioplasty, Preformed, Alterable;
Fastener, Plate, Cranioplasty

DEVICE CLASSIFICATION: Class II, 21 CFR 882.5320 and 882.5360

PREDICATE DEVICE: Aesculap's Craniofix Titanium Clamp System

DESCRIPTION: Synthes Cranial Flap Twist Clamp consists of two clamp discs with a clamp shaft in between the discs. The disc diameters range between 8.0 mm to 20 mm. The Cranial Flap Twist Clamp is MRI safe and is for single use only.

INTENDED USE: Synthes Cranial Flap Twist Clamp is intended to reattach a cranial bone flap to the surrounding Cranium after a craniotomy procedure.



JUL 20 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Sheri L. Musgung
Synthes (USA)
1690 Russell Road
Paoli, Pennsylvania 19301

Re: K991860
Trade Name: Synthes Cranial Flap Twist Clamp
Regulatory Class: II
Product Code: GXN
Dated: May 27, 1999
Received: June 1, 1999

Dear Ms. Musgung:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895.

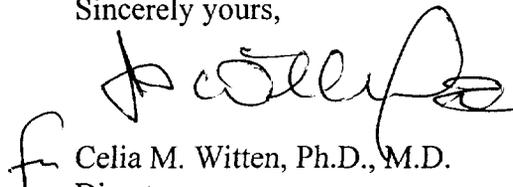
A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 – Ms. Sheri L. Musgnung

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten". The signature is written in a cursive style with a large initial "C" and "W".

Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure



2.0 Indications for Use Statement

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510(k) Number (if known): K991860

Device Name: Synthes Cranial Flap Twist Clamp

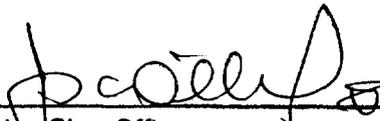
Indications For Use:

Synthes Cranial Flap Twist Clamp is intended to reattach a cranial bone flap to the surrounding Cranium after a craniotomy procedure.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use OR Over-The-Counter Use
(Per 21 CFR 801.109)



(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K991860